UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,810	11/05/1998	WENDA C. CARLYLE	1416.25US02	2290

22865 7590 04/07/2004

ALTERA LAW GROUP, LLC
6500 CITY WEST PARKWAY
SUITE 100
MINNEAPOLIS, MN 55344-7704

EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/07/2004

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/186,810	CARLYLE ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8-10,13-15,28,29 and 33-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *28,29,33,43 and 44* is/are allowed.

6)☒ Claim(s) *1,3,4,8-10,13,15,34,35 and 38-41* is/are rejected.

7)☒ Claim(s) *14,36,37 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8, 10, 13, 15, 34, 35, and 38-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 14, 21, and 29 of copending Application No. 09/014,087. The present claims are obvious over the copending claims because the same embodiment is set forth herein such that the claims set read on each other and are clearly obvious in view of each other.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al (US 5,308,641) where the substrate as claimed is the polyalkylimine-coated tissue of Cahalan and the growth factors are coated via glutaraldehyde (a crosslinking agent) to it; see especially column 4, lines 20-43 and column 6, lines 8-28 and the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that "fixed" and "crosslinked" are synonymous in the tissue graft implant art. Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of a normal cell layer"; see column 1, lines 33-43. For this reason, it stimulates the "association of viable cells with the substrate" as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan discloses medical devices/implants where the crosslinking agent glutaraldehyde attaches the growth factor biomolecule and to the substrate-spacer. Cahalan's solid

surface can be made of human or animal tissues, but Cahalan lacks the types of tissues claimed.

However, Goldstein teaches that it was known to make similar medical devices/implants out or heart valves, pericardial tissue and the like; see the whole document, especially column 3, lines 14-24.

Therefore, it is the Examiner's position that it would have been obvious to use heart valve or pericardial tissue for Cahalan's solid surface in order to reduce the risk of disease transmission and cost over using human animal tissue. Furthermore, it would have been obvious to use these tissues for the same reasons that Goldstein desires the same.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al in view of Bayne et al (EP 0476983).

With regard to claim 13, Cahalan fails to disclose the VEGF claimed even though it discloses many other growth factors therewith. Bayne teaches that it was known to use VEGF as the growth factor in a similar fashion within the same art; see the whole document.

Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as the growth factor of Cahalan so that the implant could be successfully implanted in vascular regions of the body.

Claim 41 is rejected under 35 U.S.C. 102(a) as being anticipated by Sharp et al (WO98/00695). Sharp anticipates the claim because the body of the claim does not require the preamble for completeness such that Tat protein bound to a test substrate

reads on the claim language; see page 17, line 27 to page 28, line 1. The Examiner asserts that claim 41 does not require any particular amount of growth factor. In fact, it appears to only require one molecule of growth factor because no effective amount has been claimed. Furthermore, the Tat protein of Sharp inherently stimulates attachment of viable cells to the substrate, because it is the same molecule as in Applicants claim.

Allowable Subject Matter

Claims 28, 29, 33, 43, and 44 are allowed over the prior art of record.

Claims 14, 36, 37, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are not considered persuasive.

With regard to the traversal of the double patenting rejection, the Examiner notes that no reasons were given for the distinctness of the two claims sets; only the Applicants opinion was given. For this reason, no further comment is deemed necessary.

In response to the argument traversing the Cahalan rejection that Cahalan lacks direct crosslinking of the growth factor to the substrate without a spacer molecule, the Examiner asserts that the claims do not preclude a spacer molecule and that the claims are read on by Cahalan. For this reason, this argument is not commensurate with the scope of the claims. Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that the crosslinking agent is used to attach polyalkylimine to the surface not the biomolecules. In reviewing Cahalan, the Examiner found the opposite to be true. Rather, the crosslinking agent (an aldehyde) crosslinks the surface and provides aldehyde functionalities to the surface to bind biomolecules; see column 2, line 66 to column 3, line 3. Furthermore, the Examiner asserts that the fact that Cahalan is concerned with attaching spacer molecules to a substrate does not mean the disclosure thereof does not anticipate the claim language.

Applicants also suggest that Cahalan does not teach stimulation of the association of viable cells to the substrate as claimed. However, Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of a normal cell layer"; see column 1, lines 33-43. For this reason, the claim language is considered to be fully met in this regard.

Applicants traverse the use of Goldstein as a teaching reference because they say it is directed mainly to cell removal. However, upon review of Goldstein, it is clear that it also extensively teaches coating a cell free tissue substrate with adhesion factors and then attaching cells thereafter to make non-immunogenic implants; see the abstract. For this reason, the traversal is considered unpersuasive.

In response to the traversal of the Sharp rejection that there is no evidence that the Tat protein of Sharp stimulates the attachment of viable cells to the substrate, the Examiner asserts that claim 41 does not require any particular amount of growth factor.

In fact, it appears to only require one molecule of growth factor because no effective amount has been claimed. Furthermore, the Tat protein of Sharp inherently stimulates attachment of viable cells to the substrate, because it is the same molecule as in Applicants claim. One cannot get a patent on the discovery of a new property in an otherwise old device.

In response to Applicants' argument that Sharpe is not directed to the presently claimed invention, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738